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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,290	03/03/2004	Frank S. D'Amelio SR.	45437	3540

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EXAMINER	
ROBERTS, LEZAH	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/791,290	D'AMELIO ET AL.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9,11-17,19,20,22-25 and 27-29 is/are rejected.

7)☒ Claim(s) 10,18,21 and 26 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date A and B.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims

Claim Rejections - 35 USC § 112 - Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1) Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites the limitation "the addition of folic acid" in the last line of the claim. The claim makes reference to the addition of folic acid to the composition of claim 1. The composition of claim 1 already has folic acid. There is insufficient antecedent basis for this limitation in the claim.

2) Claims 4-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is dependent on itself and is unclear as to what claim it is dependent upon.

3) Claims 17 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The two claims seem to be based on that of claim 9, which sets the limitation of at least one of the claimed species. It is unclear

whether or not this is the case for claims 17 and 28, therefore the claims will be treated the same as claim 9. (Stated alternatively, the facts of record make it unclear whether claims 17 and 28 recite a mixture of all components, or merely a list of alternatives as recited in claim 9).

Claim Rejections - 35 USC § 102 - Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-5, 9, 11-13, 15, 17 and 20-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Koenig et al. (US 2004/0039353).

Koenig et al. teach wet wipes comprising a pathogen selective antimicrobial agent and an optional broad-spectrum antimicrobial agent (see abstract). The liquid carrier for the compositions includes water, a pharmaceutically acceptable carrier (paragraph 0016), which encompasses the instant claims. Suitable natural broad spectrum antimicrobial agents include, for example, aloe vera, folic acid, calendula flower, echinacea purpurea tops, gota kola extract, chlorophyll, phytoplenolin (Centipeda) extract, chamomile flower, blood root, prickly ash bark, green tea leaf, oregano leaf, peppermint oil, cinnamon bark,

eucalyptus leaf, lavender oil, bio-saponin concentrate, olive leaf extract, black walnut green hulls, clove leaf, thyme herb, grapefruit seed extract, vegetable glycerin, and combinations thereof (paragraph 0034 and claims), which encompasses the instant claims specifically claims 9, 17 and 28. The reference anticipates the instant claims insofar as it discloses composition and methods for controlling bacteria growth. The intended use of the compositions carries no weight in determining the patentability of the instant claims because the compositions disclosed by the reference comprise substantially the same compounds, i.e., aloe vera, folic acid, calendula flower, echinacea purpurea tops, gota kola extract, chlorophyll, phytoplenolin (Centipeda) extract, chamomile flower, blood root, prickly ash bark, green tea leaf, oregano leaf, peppermint oil, cinnamon bark, eucalyptus leaf, lavender oil, bio-saponin concentrate, olive leaf extract, black walnut green hulls, clove leaf, thyme herb, grapefruit seed extract, vegetable glycerin, and combinations thereof, as compositions disclosed and claimed by the Applicant. Accordingly, in regards to the instant claims, one would have reasonably expected that the compositions of the reference have substantially the same properties, the ability to inhibit bacteria growth in the oral cavity, as the applicant's compositions, since the compositions of the reference and the compositions of the instant claims are substantially the same.

Claim Rejections - 35 USC § 103 - Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 1-9, 11, 12-17, 19-20, 22-25 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kosbab (US 2001/0031744) in view of Close (US 2002/0044977).

Kosbab teaches oral compositions to treat disorders associated with disease conditions such as dental caries. The disclosed compositions are useful in wound treatment and in the treatment of dental and periodontal disease. They comprise various components that add different therapeutic benefits. One formula for wound healing, formula IID comprises folic acid (100μg to 10,00mg), coenzyme Q10 (4mg to 400mg) and aloe vera (10mg to 50,000mg, all dosages are per day) (page 4 and 21), which meet several of the criteria of the instant claims. Folic acid supplements diet deficiencies, coenzyme Q10 is an antioxidant, and aloe vera promotes wound healing.

The dental formulations include coenzyme Q10, vitamin E and folic acid, which encompasses claim 8 and 29. The reference specifically provides compositions and methods for the treatment of slow-to heal or recurrent wounds and gum and tooth disorders including periodontal disease. Preferred compositions are for oral administration. The healing formulations for topical application to wound sites include ointments (paragraph 0009-0011). The reference differs from the instant claims insofar as it does not teach the compositions comprise an extract of *Centipeda* genus.

Close teaches an aqueous alcoholic extract from plant genus *Centipeda* in an orally acceptable carrier in the oral treatment of medical conditions that include treatment of rashes, allergic reactions, inflammations, bacterial infections or gastrointestinal disorders, which encompasses claim 15 as well as the pertinent method claims wherein bacteria growth and inflammation are treated. The compositions comprise *Centipeda cunninghami*, as recited in claim 5, which is obtained by extraction of dried plant material with aqueous ethanol, comprising 30% ethanol/70% water or a range of strengths, which encompasses claims 5-6 and 16. The amount of the extract may range from 2.1% to 20% of the composition. The extract may be combined with one or more of the following carriers such as skin protectants, e.g. olive oil; humectants, e.g. glycerin; solvents, e.g. water; herbal actives e.g. aloe vera; essential oils, e.g. sandalwood oil and lavender oil); suspension agents e.g. fractionated coconut oil; anionic emulsifying agents; antiseptics; antibacterials; healing agents; germicides e.g. tea tree oil; anti-inflammatories; skin fresheners; humectants; antioxidants; herbal actives; essential oils, e.g. eucalyptus oil and peppermint oil; and deodorizing agents,

e.g., chlorophyll. The compositions may be delivered orally in the form of a tablet, mouthwash, mouth gel, mouth lotion, gargle solution and toothpaste, which encompasses claim 11 and 20. They may also be applied topically, e.g., in creams, paints, sprays, pastes, liniments, lotions and ointments (paragraph 0019). The disclosed vitamin E cream composition comprises glycerin (10.2%), *Centipeda* plant extract (2.1%), and aloe vera (10.0%), which encompasses claim 14 and 21. The aloe vera content ranges from 6% to about 25%. The reference differs from the instant claims insofar as it does not teach using folic acid or coenzyme Q10 in the compositions.

It would have been obvious to one of ordinary skill in the art to have added a *Centipeda* plant extract and aloe vera to the compositions for wound healing treatment of periodontal disease and dental caries of the primary reference motivated by the desire to decrease inflammation associated with the treated conditions as disclosed by the secondary reference.

In regards to claims 2, 7, 14 and 27, normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. In re Aller 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to have varied amounts motivated by the desire to achieve the desired effects.

2) Claims 1-9, 11, 12-16, 19-20, 22-25 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Close (US 2002/0044977) in view of Masterson et al. (US 6,200,550).

Masterson et al. teach oral compositions comprising coenzyme Q10, folic acid and vitamin E. The disclosed oral care compositions are used for treating and ameliorating the symptoms of gingivitis and periodontal disease. The compositions comprise coenzyme Q10 combined with a solubilizing agent. The solubilizing agent is capable of fully solubilizing coenzyme Q10 in water based oral care composition and is pharmaceutically acceptable (col. 4, lines 11-21), which encompasses the instant claims. Dental studies in humans have demonstrated a deficiency of coenzyme Q10 in the gingiva tissues of individuals with gum disease and clinical studies have shown that coenzyme Q10 improved diseased gingiva tissues and a decrease in sub-gingival microbes has been observed, which encompasses the method claims' criteria of inhibiting bacteria growth (col. 1, lines 31-44). The coenzyme may be included in the compositions at concentrations ranging from 0.001% to 20% depending on the type of composition such as mouthwash or toothpaste (col. 4, lines 42-56), as recited in claims 2, 7, 14 and 27. The compositions may also include other active ingredients, such as, anti-bacterials form 0.1% to 5% (col. 7, lines 7-8), anti-inflammatory agents and healing agents in the amounts of about 0.01% to about 10% (col. 7, lines 34-37). Also included are glycerin and flavors such as peppermint oil and spearmint oil, which encompasses claim 9, 17 and 28. The reference differs from the instant claims insofar as it does not teach the composition comprises an extract of *Centipeda* genus and aloe vera.

The secondary reference is discussed above. Close teaches oral compositions comprising *Centipeda* plant extract, aloe vera, glycerine and vitamin E. The reference differs from the instant claims insofar as it does not disclose using coenzyme Q10 and folic acid in the oral compositions.

It would have been obvious to one of ordinary skill in the art to have added a *Centipeda* plant extract and aloe vera to the compositions of the primary reference motivated by the desire to treat inflammation and to heal wounds associated with gingivitis and periodontal disease as disclosed by the secondary reference.

3) Claims 1, 4-5, 8-9, 11-13, 15, 17, 20-25 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Romanowski et al (US 2005/0158252).

Romanowski et al. teach methods and compositions for oral hygiene. The compositions and methods are easy to use and comprise antimicrobial and anti-plaque agents. The conditions treated by the oral hygiene product is include oral disease, maintaining oral health, decreasing or eliminating bad breath, whitening teeth, gum deterioration, and tooth decay (paragraph 0060). The compositions may be incorporated into toothpaste, lozenges, lollipops, tablets, flash melt formulations, gums, candy or beverages (paragraph 0062), which encompasses claims 11 and 20. Ingredients that may be included in the oral compositions include those that are known to kill microorganisms, reduce inflammation and rebuild damaged tissue such as aloe vera, folic acid, calendula flower, Echinacea pupurea, gota kola extract, chlorophyll, phytoplenolin (C*entipeda*) extract, chamomile flower, blood root, prickly ash bark, green

tea leaf, oregano leaf, peppermint oil, cinnamon bark, bee propalis, eucalyptus leaf, lavender oil, bio-saponin, co-enzyme Q-10, olive leaf extract, black walnut green hulls, clove leaf, thyme herb, grapefruit seed extract and vegetable glycerin (paragraph 0058), which encompasses the instant claims. The compositions may also include glycerin and vitamin E (see table 1). As will be appreciated by those skilled in the art, substitutions may be made with similar or equivalent ingredients. All such substitutions and replacements are considered to be within the scope of the present invention.

It would have been obvious to one of ordinary skill in the are to have made dentifrices included different combinations of the listed ingredients because those skilled in the are recognize such substitutions and combination will produce similar results of those in the disclosed reference.

Allowable Subject Matter

1) Claims 10, 18, 21 and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

2) The following is a statement of reasons for the indication of allowable subject matter: the disclosed composition are concise and it would not be obvious to one of ordinary skill in the art to combine the various ingredients disclosed by the objected claims in the recited percentages. The disclosed composition in this combination and percentages are not known in the art.

Claims 1-9, 11-17, 19-20, 22-25 and 27-29 are rejected.

Claims 10, 18, 21 and 26 are objected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lezah Roberts
Patent Examiner
Art Unit 1614

Frederick Krass
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